

# 1 Synopsis

<b>Study Title</b>	<b>A Phase II, Open-label Study to Assess Safety and Clinical Utility of <math>^{68}\text{Ga}</math>-THP-PSMA PET/CT in Patients with High-risk Primary Prostate Cancer or Biochemical Recurrence after Radical treatment</b>	
<b>Short Title</b>	$^{68}\text{Ga}$ -THP-PSMA PET/CT imaging in high-risk primary prostate cancer or biochemical recurrence of prostate cancer.	
<b>Study Design</b>	This is a Phase II, open-label study to evaluate the safety and clinical utility of gallium 68-trishydroxypyridinone-prostate-specific membrane antigen ( $^{68}\text{Ga}$ -THP-PSMA) Positron Emission Tomography (PET)/Computed Tomography (CT) in patients with high-risk primary prostate cancer (PCa) or with biochemical recurrence (BCR) of PCa.	
<b>Study Patients</b>	<ul style="list-style-type: none"> <li>Group A: Patients who have been diagnosed with high-risk primary PCa and indicated for primary radical curative therapy;</li> <li>Group B: Patients with BCR being considered for radical salvage treatment (with curative intent), having had primary radical curative prostatectomy performed at least 3 months before enrolment;</li> <li>Group C: Patients with BCR being considered for radical salvage treatment (with curative intent), having had primary radical curative radiotherapy (but no surgery) performed at least 3 months before enrolment.</li> </ul>	
<b>Planned Sample Size</b>	Recruitment of approximately 60 patients.	
<b>Planned Study Period</b>	Patient recruitment is planned to start: June 2018 Last patient in: End December 2018	
	<b>Objectives</b>	<b>Endpoints</b>
<b>Primary</b>	Evaluation of $^{68}\text{Ga}$ -PSMA PET impact on the management of patients with PCa cancer in the setting of: <ol style="list-style-type: none"> <li>BCR in patients treated with radical prostatectomy</li> <li>BCR in patients treated with radiotherapy</li> <li>newly diagnosed high-risk PCa</li> </ol>	Change in-patient management as a result of $^{68}\text{Ga}$ -PSMA PET documented after scan, compared with pre-scan management plan
<b>Secondary</b>	Evaluation of safety of $^{68}\text{Ga}$ -PSMA in patients with PCa	Adverse events: Clinically significant changes in heart rate, blood pressure, electrocardiogram, urinalysis and baseline serum haematology and biochemistry profile
<b>Tertiary (exploratory)</b>	Evaluation of technical feasibility of $^{68}\text{Ga}$ -PSMA in patients with PCa	Technical success/failure of study, artefacts, pitfalls in interpretation
	Correlation of PSMA on imaging and PSMA within tumour	Correlation of degree of uptake on PET/CT with histopathological staining of PSMA as per standard of care where histology is available